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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,154	06/22/2001	Ramesh Wariar	112713-131	8167
29200	7590	04/21/2005	EXAMINER	
BAXTER HEALTHCARE CORPORATION RENAL DIVISION 1 BAXTER PARKWAY DF3-3E DEERFIELD, IL 60015			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 04/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/888,154	WARIAR ET AL.
	Examiner	Art Unit
	Patricia M Bianco	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-14,17-21,23-27,29,30 and 32-37 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5-14,17-21,23-27,29,30 and 32-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 June 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: Detailed Action.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 5-14, 17-21, 23-27, 29, 30, & 32-37 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following claimed subject matte be shown or the feature(s) canceled from the claim(s):

A controller or control device; control display; hemodialysis machine; cordless interface and electrical communication for hemodialysis machine.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology, namely capable, comprising, and adapted. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites "*The method of Claim 38*" as its preamble; however, claim 38 is cancelled which renders the claim indefinite. Correction is required

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 8, 10, 17, 27, & 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Miki et al (5,078,682). Miki et al. teaches of a liquid transfusion apparatus that comprises a capacitive sensor for use in monitoring if a needle is accidentally removed from a blood vessel. If the needle were to be removed from the vessel, blood would appear. The sensor has a housing, seen to be equivalent to a sensor holder. The apparatus further includes a CPU or control device, including a display unit and alarm, for monitoring sensor and system. The sensor's detecting

wetness and the needle are never positively claimed. The sensor is further limited as being "capable of detecting wetness due to blood" in claim 1 and it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. The recitation that the holder is "adapted to secure the sensor in juxtaposition to the needle" has not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. Therefore, the recitation that the needle be "venous" is also not positively recited and therefore not given any patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 24, 29, & 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al. ('682) in view of Vantard (4,655,742).

Miki et al. discloses the invention substantially as claimed (see rejection *supra*), however, does not specifically teach that the sensor is used in a hemodialysis/dialysis method. Vantard teaches of an apparatus and method for processing blood extracorporeally through a semipermeable membrane for filtering the blood (i.e. hemodialysis and dialysis). The system includes a sensor for monitoring fluid pressure in the line to monitor for a change in pressure as a result of the needle becoming removed from the patient, and alarm if it occurs. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the teachings of Miki et al. to use the sensor in a hemodialysis/dialysis procedure as taught by Vantard, since it is important to quickly correct a needle dislodgement to avoid air infiltration of the vessel.

Claims 5, 6, 9, 11-14, & 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al. ('682) in view of Goodman (E-Z-Em, Inc. WO 99/26686). Miki et al. discloses the invention substantially as claimed (see rejection *supra*), however, does not specifically teach that the sensor comprises an electrode or a control device attached to a patient. Goodman discloses an extravasation device comprising

electrodes (18/20) contained within an electrode patch (12), which is comprised of a cavity of two bodies 17/19 (i.e. housing). The device has a clip (28) that is connected to a control device (29) via a wire, and therefore the control device is attached to the patient. At the time of the invention, it would have been an obvious matter of design choice to modify the sensor of the system of Miki et al. with the extravasation device of Goodman as a substitution of parts, since applicant has set forth no criticality as to the structure and function of the sensor and both perform the same function, that of monitoring a needle for withdrawal from a vessel.

Claims 13, 14, 19, 20, & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al. & Goodman as applied to claims 17 & 18 above, and further in view of Bandeian, Jr. et al. (6,445,304). Miki et al. & Goodman discloses the invention substantially as claimed (see rejection *supra*), however, does not specifically teach that the sensor comprises a sterile pad. Bandeian, Jr. teaches of the addition of a porous material, such as gauze, bandage, or other porous medical item, adjacent an electrical needle dislodgement sensing means. The use of the porous material is to provide a buffer between the patient's skin and the sensing device as well as provide a surface for blood to absorb at the bleed or dislodgement site. At the time of the invention, it would have been an obvious matter of design choice to modify the sensor of Miki et al. & Goodman to include a porous material to provide a buffer between the patient's skin and the sensing device as well as provide a surface for blood to absorb at the bleed or dislodgement site.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Burbank et al. (2003/0128125) disclose analogous prior art, however, is not prior art since its effective filing date is after the effective filing date of the instant application.

Shekalim (6,425,878) & Hirschman (6,751,500) disclose analogous apparatus and methods for determining needle extravasation using capacitive sensors.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

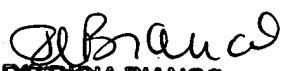
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 16th, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER